STATE OF MICHIGAN

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner of Financial and Insurance Regulation

In the matter of	
XXXXX	
Petitioner	
v	File No. 123528-001-SF
Blue Cross Blue Shield of Michigan Respondent	

Issued and entered
this __20th___ day of January 2012
by R. Kevin Clinton
Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On September 22, 2011, XXXXX (Petitioner) filed a request with the Commissioner of Financial and Insurance Regulation for an external review under Public Act No. 495 of 2006, MCL 550.1951 *et seq*. After a preliminary review of the material submitted, the Commissioner accepted the request on September 29, 2011.

The Petitioner is enrolled for health care benefits through the Charter Township of XXXXX, a local unit of government with a self-funded health plan under Act 495. The plan is administered by BCBSM. Section 2(2) of Act 495, MCL 550.1952(2), authorizes the Commissioner to conduct this external review as though the Petitioner were a covered person under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq*.

The Petitioner's health care benefits are defined in the Blue Cross Blue Shield of Michigan (BCBSM) *Blue Shield 65 G-I Benefit Certificate* which provides coverage secondary to Medicare. Because this review involves medical issues, the Commissioner assigned the case to an independent review organization which provided its analysis and recommendation to the Commissioner on October 13, 2011.

II. FACTUAL BACKGROUND

On June 2, 2011, the Petitioner received an injection of Xiaflex, a nonsurgical treatment for patients with Dupuytren's contracture. The condition causes an abnormal thickening of the tissue into cords in the palm of the hand. Over time, the thickening in the cords can cause one or more

fingers to bend toward the palm so the patient cannot straighten them. Xiaflex is injected into the cords to reduce the contractures.

Medicare, as Petitioner's primary health plan, paid for a portion of this treatment. The amount in dispute after Medicare's payment is \$675.22. The Petitioner requested that BCBSM provide secondary coverage. BCBSM denied coverage ruling that the treatment was investigational for the treatment of Petitioner's condition.

The Petitioner argues that the injections are not investigational and that BCBSM is required to pay all the deductibles and copayments for care approved by Medicare.

The Petitioner appealed through BCBSM's internal grievance process. After a managerial-level conference, BCBSM maintained its decision and issued a final adverse determination letter dated August 15, 2011.

III. ISSUE

Did BCBSM properly deny coverage for the Petitioner's Xiaflex injection?

IV. ANALYSIS

The certificate language is clear that experimental services are not a covered benefit. There is nothing in the certificate that requires BCBSM to pay for an experimental service even if Medicare as the primary carrier pays for the service.

The question of whether the Xiaflex injections are experimental for treatment of the Petitioner's condition was presented to an independent review organization (IRO) for analysis as required by Section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6). The IRO physician reviewer is certified by the American Board of Orthopedic Surgery, is a member of the American Academy of Orthopedic Surgeons, and is in active practice. The IRO reviewer's report contained the following analysis:

There are inadequate well done studies in the peer reviewed literature establishing Xiaflex as safe and effective for the treatment of Dupuytren's contracture when the medical necessity inclusion criteria are met, as they are in this case. . . . In this case, the enrollee is sixty five (65) years old with Dupuytren's contracture including a palpable cord and 90 degree contracture of the right ring finger PIP joint.

* * *

The goal of treatment with XiaflexTM when injected directly into Dupuytren's cord is collagen disruption so the contracture may be reduced and range of motion may be improved.

The treatment of Dupuytren's depends on the severity of the disease. The disease initially can be managed with observation and non-surgical therapy. It will regress without treatment in about 10% of patients. . . . Dupuytren's contracture can be treated medically with steroid injections into the nodule. This has been shown to reduce the need for surgery. Surgical intervention with open fasciectomy or fasciotomy is recommended when contracture is progressing and functional impairment is considerable. Timing of surgical intervention varies, but surgery is usually performed when the MP joint contracture exceeds 40° or when the PIP joint contracture exceeds 20°. The longer a deformity is present, the greater the risk of an irreversible joint contracture. Surgery is usually successful, but recurrence is common.

The reviewer then summarized the published medical studies concerning the treatment of Dupuytren's contracture and concluded that the requested procedure is experimental/investigational for the treatment of the Petitioner's condition.

The Commissioner is not required in all instances to accept the IRO's recommendation. However, the IRO recommendation is afforded deference by the Commissioner. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principal reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16) (b). The IRO reviewer's analysis is based on expertise and professional judgment and the Commissioner can discern no reason why the recommendation should be rejected in the present case.

The Commissioner finds that BCBSM's denial of Xiaflex injections as investigational/experimental for treatment of the Petitioner's condition is consistent with the terms of the certificate.

V. ORDER

Blue Cross Blue Shield of Michigan's August 15, 2011, final adverse determination is upheld. BCBSM is not required to cover the Petitioner's Xiaflex injection.

This is a final decision of an administrative agency. Under MCL 550.1915(1), any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or in the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

R. Kevin Clinton

R. Kevin Clinton Commissioner